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**STATE OF WISCONSIN
Division of Hearings and Appeals**

In the Matter of

[REDACTED]
[REDACTED]
[REDACTED]

DECISION

MPA/171735

PRELIMINARY RECITALS

Pursuant to a petition filed January 29, 2016, under Wis. Stat. § 49.45(5), and Wis. Admin. Code § HA 3.03(1), to review a decision by the Division of Health Care Access and Accountability in regard to Medical Assistance, a telephone hearing was held on March 08, 2016.

The issue for determination is whether the petitioner is entitled to medical assistance reimbursement for Harvoni.

There appeared at that time and place the following persons:

PARTIES IN INTEREST:

Petitioner:

[REDACTED]
[REDACTED]
[REDACTED]

I

Respondent:

Department of Health Services
1 West Wilson Street, Room 651
Madison, Wisconsin 53703

By: [REDACTED], [REDACTED] (written appearance only)
Division of Health Care Access and Accountability
1 West Wilson Street, Room 272
P.O. Box 309
Madison, WI 53707-0309

ADMINISTRATIVE LAW JUDGE:

Peter McCombs
Division of Hearings and Appeals

FINDINGS OF FACT

1. Petitioner is a resident of Dane County.
2. The petitioner, by his provider, [REDACTED], submitted a prior authorization (PA) request for the drug Harvoni, on December 1, 2015. Exhibit 2.

3. The Division of Health Care Access and Accountability denied the petitioner's request for Harvoni on December 15, 2015, because he did not meet the level of liver damage required for approval.
4. Petitioner is coinfectd with HIV, and also has diagnoses of diabetes and low-grade thrombocytopenia.

DISCUSSION

Federal medical assistance rules allow, but do not require, states to pay for prescription drugs. 42 C.F.R. § 440.225. Wisconsin pays for prescription drugs (Wis. Admin. Code § DHS 107.10), but controls their cost by dividing them into two classes, preferred and non-preferred. Preferred drugs are usually older, often generic, and almost always less expensive than non-preferred drugs. Wisconsin requires prior authorization before paying for non-preferred prescription drugs, which it refers to as those it “has determined entail substantial cost or utilization problems for the MA program.” Wis. Admin. Code, § DHS 107.10(2)(d).

The petitioner seeks payment from the medical assistance program for Harvoni to treat his liver damage from Hepatitis C. Harvoni is a non-preferred drug requiring prior authorization when used to treat hepatitis C because each treatment costs between \$63,000 to \$189,000.

The petitioner and his provider must prove by the preponderance of the credible evidence that the drug is needed. As with any request for a medical assistance service, the petitioner must prove, among other things, that the drug is medically necessary and appropriate. The Department must consider the cost of the service, the extent to which less expensive alternative services are available, and whether the service is an effective and appropriate use of available services. Wis. Admin. Code § DFS 107.02(3)(e)1.,2.,3.,6. and 7. “Medically necessary” means a medical assistance service under ch. HFS 107 that is “[r]equired to prevent, identify or treat a recipient's illness, injury or disability” and, among other things, “[w]ith respect to prior authorization of a service and to other prospective coverage determinations made by the department, is cost-effective compared to an alternative medically necessary service which is reasonably accessible to the recipient. Wis. Admin. Code, § DHS 101.03(96m)(a) and (b)8.

The department has developed guidelines concerning when to pay for Harvoni. These guidelines, which are found in the department's online ForwardHealth update 2015-27, at <https://www.forwardhealth.wi.gov/kw/pdf/2015-27.pdf>, allow the drug to be considered for those whose hepatitis C has advanced to any of the following stages:

Only PA requests for Harvoni® for members whose hepatitis C liver disease has advanced to any of the following stages and who are clinically ineligible for treatment with Viekira Pak™ due to a medical or medication contraindication may be considered for review:

- Compensated cirrhosis (i.e., CTP class A).
- Evidence of bridging fibrosis (e.g., Metavir score of F3 or greater).
- Serious extra-hepatic manifestations of HCV.

In addition, only PA requests for members who have chronic hepatitis C genotype 1 infection will be considered for review.

Id.

Prior authorization requests for Harvoni will be denied in the following circumstances:

- The member does not have a medical or medication contraindication for treatment with Viekira Pak™.
- The member has acute hepatitis C.
- The member has a significant or uncontrolled concurrent disease (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease, thyroid disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C). (Note: If the member is currently on a liver transplant wait list with an elevated MELD score, individual circumstances will be considered for review.)
- The member has received a liver transplant.
- The member is currently abusing drugs or alcohol. Members with compensated cirrhosis must be abstinent from alcohol for the six months prior to and during HCV treatment. Members must no longer be abusing drugs for at least six months prior to HCV treatment. Active participation in a recovery program is required for members with a recent history of alcohol or drug abuse.
- The member has taken a prior course of therapy with Harvoni® or Sovaldi™.
- The member has not been compliant with approved hepatitis C treatment regimen.

Id.

The Division of Health Care Access and Accountability denied the petitioner's request because it did not consider his hepatitis C severe enough to warrant approval under the guidelines. Specifically, the respondent asserts that the petitioner's provider has failed to provide documentation confirming that, 1) the petitioner has compensated cirrhosis (i.e. CTP class A) of the liver, and 2) petitioner has a Metavir score of F3 or greater. The respondent provided a detailed explanation of the basis for its decision, and, based upon the entirety of the record before me, I am unable to conclude that petitioner has successfully rebutted the respondent's argument.

Petitioner's provider asserted that petitioner has compensated cirrhosis of the liver, but provided no documentation to support its conclusion. The respondent wrote:

It is unclear how the provider determined the member has compensated cirrhosis, there were no additional tests included that would indicate the member has compensated cirrhosis, nor was there a physical exam showing any signs or symptoms of cirrhosis.

Exhibit 3.

I must concur. None of the medical records or correspondence from petitioner's providers (see, Exhibit 4), provide and basis for the compensated cirrhosis claim.

With regard to the Metavir score, petitioner testified that he was at an F3 level. The respondent contends, however, that his FibroScan results actually translate to a score of F2. The respondent wrote:

... The prescriber indicated the member had an MRI on 6/27/2014 and a FibroScan on 11/25/2015. The included liver CT scan was unremarkable, with no liver lesions seen. The member's FibroScan results showed a liver stiffness value of 10.1 kPa. ... [F]or members with HCV and HIV coinfection a FibroScore core of 10.1 kPa translates to a Metavir score of F2.

Exhibit 3.

I find nothing in the record to dispute the respondent's conclusion in this regard.

CONCLUSIONS OF LAW

The respondent correctly denied petitioner's PA for Harvoni, as his provider did not establish that petitioner satisfied the Harvoni approval criteria.

THEREFORE, it is

ORDERED

That petitioner's appeal is hereby dismissed.

REQUEST FOR A REHEARING

You may request a rehearing if you think this decision is based on a serious mistake in the facts or the law or if you have found new evidence that would change the decision. Your request must be **received within 20 days after the date of this decision**. Late requests cannot be granted.

Send your request for rehearing in writing to the Division of Hearings and Appeals, 5005 University Avenue, Suite 201, Madison, WI 53705-5400 **and** to those identified in this decision as "PARTIES IN INTEREST." Your rehearing request must explain what mistake the Administrative Law Judge made and why it is important or you must describe your new evidence and explain why you did not have it at your first hearing. If your request does not explain these things, it will be denied.

The process for requesting a rehearing may be found at Wis. Stat. § 227.49. A copy of the statutes may be found online or at your local library or courthouse.

APPEAL TO COURT

You may also appeal this decision to Circuit Court in the county where you live. Appeals must be filed with the Court **and** served either personally or by certified mail on the Secretary of the Department of Health Services, 1 West Wilson Street, Room 651, Madison, Wisconsin 53703, **and** on those identified in this decision as "PARTIES IN INTEREST" **no more than 30 days after the date of this decision** or 30 days after a denial of a timely rehearing (if you request one).

The process for Circuit Court Appeals may be found at Wis. Stat. §§ 227.52 and 227.53. A copy of the statutes may be found online or at your local library or courthouse.

Given under my hand at the City of Madison,
Wisconsin, this 22nd day of April, 2016

\sPeter McCombs
Administrative Law Judge
Division of Hearings and Appeals



State of Wisconsin\DIVISION OF HEARINGS AND APPEALS

Brian Hayes, Administrator
Suite 201
5005 University Avenue
Madison, WI 53705-5400

Telephone: (608) 266-3096
FAX: (608) 264-9885
email: DHAmail@wisconsin.gov
Internet: <http://dha.state.wi.us>

The preceding decision was sent to the following parties on April 22, 2016.

Division of Health Care Access and Accountability